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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/164, 764 10/01/98 SIDRANSKY

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HM12/0820

EXAMINER

FAWLIL, A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED:

08/20/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/164,764

Applicant(s)

David Sidransky

Examiner

Anna Pawul

Group Art Unit
1653



Responsive to communication(s) filed on Jul 21, 1999

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 23-34 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 23-34 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The fax transferring the sequence listing from the parent application Serial No. 08/854,727 and the fax containing the amendment to the claims has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 23-33 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The term "organ which drains into the specimen" in claim 23 is a relative term which renders the claim indefinite. The term "organ which drains into the specimen" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what is meant by this phrase because an organ can drain into a body cavity, another organ etc. Please clarify.

4. The term "claim1" in claims 24-33 is a relative term which renders the claim indefinite. The term "claim 1" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably

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apprised of the scope of the invention. Claim 1 has been canceled, therefore it is unclear what applicant is referring to. Please clarify.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 23-34 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 48-61 of copending Application No. 08/854,727. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both employ methods of detecting various cancers by utilizing microsatellite repeats. Both sets of claims use non-tumor tissue samples such as urine and sputum to isolate DNA and both sets of claims employ the use of PCR to amplify different sections of the sample DNA. The two inventions both compare the markers of control and cancerous samples. Although the patent case contains a Markush Group the new group will read on the genus.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

8. Claims 23-26 and 28 rejected under 35 U.S.C. 102(e) as being anticipated by de la Chapelle, US Patent # 5,871,925.

De la Chapelle teaches that DNA from tumors display a change in the short repeat sequences (microsatellites) and that these differ from normal tissues (abstract and column 2, line 51-56). They also teach that the microsatellite repeats are “typically di-or tri-nucleotide repeats” (column 6, line 34-36).

In addition, de la Chapelle teaches that the DNA sample is obtained from blood or any other body tissue from which DNA can be obtained (column 3, line 57 and column 5, line 17-18).

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Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 27, 29-34 rejected under 35 U.S.C. 103(a) as being unpatentable over de la Chappelle et al. (US Patent 5,871,925) and further in view of Gonzalez-Zulueta et.al (Cancer Research, 1993), Merlo et.al (Cancer Research, 1994), and Ah-See et al..(Cancer Research, 1994).

Claim 27 is drawn to a method to detect differences in microsatellite marker length where the microsatellite marker is a tetra-nucleotide repeat.

Claims 29-33 are further limiting as they refer to a specific specimen or organ from which the DNA sample is obtained.

Claim 34 is further limiting wherein the sample is from a specimen or tumor that is external to the primary tumor or a histopathological margin sample.

The primary reference, de la Chappelle et al., discloses a method for the use of microsatellite markers to detect cancer (column 18, lines 82-96). De la Chapelle (US Patent # 5,871,925) teaches that DNA from tumors display a change in the short repeat sequences

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(microsatellites) and that these differ from normal tissues (abstract and column 2, line 51-56).

They also teach that the microsatellite repeats are “typically di-or tri-nucleotide repeats” (column 6, line 34-36). In addition, de la Chapelle teaches that the DNA sample is obtained from blood or any other body tissue from which DNA can be obtained (column 3, line 57 and column 5, line 17-18). de la Chapelle does not teach to the use of DNA samples from primary tumors or regions near primary tumors. They also do not teach that the microsatellite markers can be tetra-nuclide repeats.

Gonzalez-Zulueta, et al address instabilities that include both tri and tetra-nucleotide repeats and both expansion and deletions of the repeat units within the microsatellite markers (p.5620, lines 2-8). The reference uses bladder and colorectal cancer as examples but Gonzalez-Zulueta, et al suggests that “ this kind of instability might be common to all sporadic human cancers” (Cancer Research, 53 1993 - p. 5622, column 2, line 22-29).

In Merlo et al (p. 2098 column 2, lines 11-39) microsatellite sequences are examined in both tumors and normal tissues of the lung. Differences in the microsatellite markers are examined by amplification via PCR. The tumors that are examined are primary tumors.

Ah-See et.al teaches using microsatellite markers to analyze cancers of the head and neck (p.1617, column 1, lines 3-7).

The examiner takes note that the preceding references do not use a fluid specimen that has come from the organ in question. de la Chapelle teaches that the DNA sample is obtained

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from blood or any other body tissue from which DNA can be obtained (column 3, line 57 and column 5, line 17-18. Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of de la Chapelle pertaining to changes in microsatellite markers to detect cancer, with tetranucleotide changes in microsatellite sequences taught by Gonzalez and its application in primary tumors and organ specific tumors taught by Merlo and Ah-See to achieve the claimed inventor as a whole. One of ordinary skill in the art would have been motivated to achieve detection of tumors in sample for diagnostic and prognostic purpose as taught by de la Chapelle (see abstract).

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Pawul whose telephone number is (703) 305-0806. The examiner can normally be reached Monday-Friday 7:30 AM to 4:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bradley Sisson, can be normally reached on Monday-Thursday from 8:00 AM to 5:00 PM (EST) and whose telephone number is (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to group 180 via the PTO Fax Center located in Crystal Mall 1. Papers may be submitted Monday-Friday between 8:00 AM and 4:00 PM (EST). The faxing of such papers must conform

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with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 fax Center number is (703) 305-3014 or (703) 308-4242.

AP 8-13-99

A handwritten signature in black ink, appearing to read "Eggerton A. Campbell". The signature is fluid and cursive, with "Eggerton" on the top line and "A. Campbell" on the bottom line.

**EGGERTON A. CAMPBELL
PRIMARY EXAMINER**